

Serial No. 09/481,207

IN THE CLAIMS*I. Pending Independent Claims*

For the convenience of the Examiner, a copy of pending independent claims 23, 95, 622, 666, and 718, as they now stand in front of the Patent Office, is provided below:

E1
Sub E1
23. (Amended twice) A solid pharmaceutical composition in a dosage form that is not enteric-coated, comprising: active ingredients consisting essentially of:

(a) a non-enteric coated proton pump inhibitor selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole, or an enantiomer, isomer, derivative, free base, or salt thereof, in an amount of approximately 5 mg to approximately 300 mg; and

(b) at least one buffering agent in an amount of approximately 0.1 mEq to approximately 2.5 mEq per mg of proton pump inhibitor;

wherein the dosage form is selected from the group consisting of suspension tablet, chewable tablet, effervescent powder, and effervescent tablet.

D1

Sub E2
95. (Amended twice) A method for treating an acid-related gastrointestinal disorder in a subject in need thereof, comprising: administering to the subject the dosage form of claim 23 via a route selected from the group consisting of oral, nasogastric, and gastric tube.

D2
Sub E2

622. (Amended) A method for treating an acid-related gastrointestinal disorder in a subject in need thereof, comprising: administering to the subject a solid pharmaceutical composition in a dosage form that is not enteric-coated; wherein the composition comprises active ingredients consisting essentially of:

D3
Sub E3

Serial No. 09/481,207

Sub E4

(a) a therapeutically effective amount of a non-enteric coated proton pump inhibitor selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole, or an enantiomer, isomer, derivative, free base, or salt thereof; and

D3 Cont

(b) a buffering agent selected from the group consisting of a bicarbonate salt of a group IA metal, a calcium salt, and a magnesium salt, wherein the buffering agent is in an amount sufficient to elevate gastric acid pH of the subject's stomach to prevent or inhibit gastric acid degradation of the non-enteric coated proton pump inhibitor and achieve sufficient bioavailability of the proton pump inhibitor in the subject to elicit a therapeutic effect.

57

666. (Amended) A solid pharmaceutical composition in a dosage form that is not enteric-coated, comprising: active ingredients consisting essentially of:

D4

(a) a therapeutically effective amount of a non-enteric coated proton pump inhibitor selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole, or an enantiomer, isomer, derivative, free base, or salt thereof; and

(b) a buffering agent selected from the group consisting of sodium bicarbonate, and calcium carbonate, in an amount more than about 40 times the amount of the proton pump inhibitor on a weight to weight basis in the composition.

D5

Sub E6 E17

718. (Amended) A method for treating an acid-related gastrointestinal disorder in a subject in need thereof, comprising: administering to the subject the dosage form as recited in Claim 666 via a route selected from the group consisting of oral, nasogastric, and gastric tube.

Serial No. 09/481,207

II. Cancellation of Claims

Please cancel claims 26, 66-68, 70-72, 74-76, 82, 83, 85, 86, 91-94, 97-103, 111, 136-141, 144-163, 167-181, 184-222, 226-621, 623, 651, 655, 657-660, 662-665, 668-678, 686, 705-708, 715, 720-723, 726-728, 747-756, 760-764, and 766-861, without prejudice.

III. Addition of Claims

Please add the following claims:

¹¹³
862. (New) The composition of Claim 23, wherein the buffering agent comprises a bicarbonate salt of a Group IA metal.

¹¹⁴
863. (New) The composition of Claim 23, wherein the buffering agent comprises at least one of magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium carbonate, or magnesium silicate.

¹¹⁵
864. (New) The composition of Claim 23, wherein the buffering agent comprises at least one of calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium bicarbonate, calcium gluconate, or other calcium salts.

¹¹⁶
865. (New) The composition of Claim 23, further comprising a disintegrant, flow aid, lubricant, adjuvant, excipient, colorant, diluent, moistening agent, preservative, and pharmaceutically compatible carrier.

866. (New) The method of claim 95, wherein the composition further comprises a disintegrant, flow aid, lubricant, adjuvant, excipient, colorant, diluent, moistening agent, preservative, and pharmaceutically compatible carrier.

110

D

Serial No. 09/481,207

¹¹⁷
867: (New) The method of claim ²⁴622 wherein the composition further comprises a disintegrant, flow aid, lubricant, adjuvant, excipient, colorant, diluent, moistening agent, preservative, and pharmaceutically compatible carrier.

¹¹⁸
868: (New) The composition of Claim ⁵⁷666, further comprising a disintegrant, flow aid, lubricant, adjuvant, excipient, colorant, diluent, moistening agent, preservative, and pharmaceutically compatible carrier.

IV. *Substitution of Claims*

Substitute pending claims 23, 95, 96, 104-110, 129, 132, 133, 622, 624-650, 652-654, 656, 661, 666-667, 680-683, 685, 704, 717-719, and 745 with the corresponding amended claims, as shown below:

23. (Amended twice) A solid pharmaceutical composition in a dosage form that is not enteric-coated, comprising: active ingredients consisting essentially of:

NE (a) a non-enteric coated proton pump inhibitor selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole, or an enantiomer, isomer, derivative, free base, or salt thereof, in an amount of approximately 5 mg to approximately 300 mg; and

(b) at least one buffering agent in an amount of approximately 0.1 mEq to approximately 2.5 mEq per mg of proton pump inhibitor;

wherein the dosage form is selected from the group consisting of suspension tablet, chewable tablet, effervescent powder, and effervescent tablet.

111

D

Serial No. 09/481,207

95. (Amended twice) A method for treating an acid-related gastrointestinal disorder in a subject in need thereof, comprising: administering to the subject the dosage form of claim 23 via a route selected from the group consisting of oral, nasogastric, and gastric tube.

96. (Amended) The method as recited in Claim 95, wherein the disorder is selected from the group consisting of duodenal ulcer disease, gastric ulcer disease, gastroesophageal reflux disease, erosive esophagitis, poorly responsive symptomatic gastroesophageal reflux disease, pathological gastrointestinal hypersecretory disease, Zollinger Ellison Syndrome, and acid dyspepsia.

104. (Amended) The method as recited in Claim 95, wherein the proton pump inhibitor is omeprazole.

105. (Amended) The method as recited in Claim 95, wherein the proton pump inhibitor is lansoprazole.

106. (Amended) The method as recited in Claim 95, wherein the proton pump inhibitor is rabeprazole.

107. (Amended) The method as recited in Claim 95, wherein the proton pump inhibitor is esomeprazole.

108. (Amended) The method as recited in Claim 95, wherein the proton pump inhibitor is pantoprazole.

109. (Amended) The method as recited in Claim 95, wherein the proton pump inhibitor is pariprazole.

110. (Amended) The method as recited in Claim 95, wherein the proton pump inhibitor is leminoprazole.

Serial No. 09/481,307

D9 129. (Amended) The method as recited in Claim 95, wherein the buffering agent comprises at least one of calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium bicarbonate, calcium gluconate, or other calcium salts.

D10 132. (Amended) The method as recited in Claim 95, wherein the buffering agent is about 250 mg to about 1000 mg calcium carbonate.

133. (Amended) The method as recited in Claim 95, wherein the buffering agent is about 500 mg to about 1000 mg calcium carbonate.

NE 622. (Amended) A method for treating an acid-related gastrointestinal disorder in a subject in need thereof, comprising: administering to the subject a solid pharmaceutical composition in a dosage form that is not enteric-coated; wherein the composition comprises active ingredients consisting essentially of:

(a) a therapeutically effective amount of a non-enteric coated proton pump inhibitor selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole, or an enantiomer, isomer, derivative, free base, or salt thereof; and

L (b) a buffering agent selected from the group consisting of a bicarbonate salt of a group IA metal, a calcium salt, and a magnesium salt, wherein the buffering agent is in an amount sufficient to elevate gastric acid pH of the subject's stomach to prevent or inhibit gastric acid degradation of the non-enteric coated proton pump inhibitor and achieve sufficient bioavailability of the proton pump inhibitor in the subject to elicit a therapeutic effect.

25 624. (Amended) The method of Claim 622²⁴, wherein the calcium salt is selected from the group consisting of calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium bicarbonate, calcium gluconate, and other calcium salts.

D11

113

D

Serial No. 09/481,207

²⁶
625. (Amended) The method of Claim ²⁴622, wherein the sodium bicarbonate is in an amount from about 1000 mg to about 1680 mg.

²⁷
626. (Amended) The method of Claim ²⁴622, wherein the sodium bicarbonate is in an amount of at least about 1680 mg.

²⁸
627. (Amended) The method of Claim ²⁴622, wherein the calcium salt is calcium carbonate present in an amount from about 250 mg to about 1000 mg.

²⁹
628. (Amended) The method of Claim ²⁴622, wherein the calcium salt is calcium carbonate present in an amount from about 500 mg to about 1000 mg.

³⁰
629. (Amended) The method of Claim ²⁴622, wherein the calcium salt is calcium carbonate present in an amount of at least about 1000 mg.

³¹
630. (Amended) The method of Claim ²⁴622, wherein the buffering agent is in an amount of at least 10 mEq.

³²
631. (Amended) The method of Claim ²⁴622, wherein the buffering agent is in an amount from about 10 mEq to about 70 mEq.

³³
632. (Amended) The method of Claim ²⁴622, wherein the buffering agent is in an amount from about 20 mEq to about 40 mEq.

³⁴
633. (Amended) The method of Claim ²⁴622, wherein the proton pump inhibitor is in an amount from about 10 mg to about 100 mg.

³⁵
634. (Amended) The method of Claim ²⁴622, wherein the proton pump inhibitor is omeprazole.

³⁶
635. (Amended) The method of Claim ³⁵634, wherein the omeprazole is present in an amount of about 10 mg.

114

D

Serial No. 09/481,207

³⁷
~~636~~. (Amended) The method of Claim ~~634~~³⁵, wherein the omeprazole is present in an amount of about 20 mg.

³⁸
~~637~~. (Amended) The method of Claim ~~634~~³⁵, wherein the omeprazole is present in an amount of about 40 mg.

³⁹
~~638~~. (Amended) The method of Claim ~~634~~³⁵, wherein the omeprazole is present in an amount of about 60 mg.

⁴⁰
~~639~~. (Amended) The method of Claim ~~634~~³⁵, wherein the omeprazole is present in an amount of about 80 mg.

⁴¹
~~640~~. (Amended) The method of Claim ~~634~~³⁵, wherein the omeprazole is present in an amount of about 100 mg.

⁴²
~~641~~. (Amended) The method of Claim ~~622~~²⁴, wherein the proton pump inhibitor is lansoprazole.

⁴³
~~642~~. (Amended) The method of Claim ~~641~~⁴², wherein the lansoprazole is present in an amount of about 15 mg.

⁴⁴
~~643~~. (Amended) The method of Claim ~~641~~⁴², wherein the lansoprazole is present in an amount of about 30 mg.

⁴⁵
~~644~~. (Amended) The method of Claim ~~641~~⁴², wherein the lansoprazole is present in an amount of about 45 mg.

⁴⁶
~~645~~. (Amended) The method of Claim ~~641~~⁴², wherein the lansoprazole is present in an amount of about 60 mg.

⁴⁷
~~646~~. (Amended) The method of Claim ~~641~~⁴², wherein the lansoprazole is present in an amount of about 90 mg.

115

D

Serial No. 09/481,207

⁴⁸ 647. (Amended) The method of Claim ⁴² 641, wherein the lansoprazole is present in an amount of about 100 mg.

⁴⁹ 648. (Amended) The method of Claim ²⁴ 622, wherein the proton pump inhibitor is micronized.

⁵⁰ 649. (Amended) The method of Claim ²⁴ 622, wherein the composition is in a dosage form selected from the group consisting of a tablet, powder, suspension tablet, chewable tablet, capsule, effervescent powder, effervescent tablet, pellets, and granules.

⁵¹ 650. (Amended) The method of Claim ²⁴ 622, wherein the subject is a human.

⁵² 652. (Amended) The method of Claim ²⁴ 622, wherein the dosage form further comprises a flavoring agent.

⁵³ 653. (Amended) The method of Claim ⁵² 632, wherein the flavoring agent comprises aspartame, chocolate, root beer, peppermint, spearmint, or watermelon, and combinations of any of the foregoing.

⁵⁴ 654. (Amended) The method of Claim ²⁴ 622, wherein the composition is provided as a separate component of a kit.

⁵⁵ 656. (Amended) The method of Claim ²⁴ 622, wherein the disorder is selected from the group consisting of duodenal ulcer disease, gastric ulcer disease, gastroesophageal reflux disease, erosive esophagitis, poorly responsive symptomatic gastroesophageal reflux disease, pathological gastrointestinal hypersecretory disease, Zollinger Ellison Syndrome, and acid dyspepsia.

⁵⁶ 661. (Amended) The method of Claim ²⁴ 622, wherein the dosage form is administered once or twice a day.

116

D

Serial No. 09/481,207

666. (Amended) A solid pharmaceutical composition in a dosage form that is not enteric-coated, comprising: active ingredients consisting essentially of:

- (a) a therapeutically effective amount of a non-enteric coated proton pump inhibitor selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole, or an enantiomer, isomer, derivative, free base, or salt thereof; and
- (b) a buffering agent selected from the group consisting of sodium bicarbonate, and calcium carbonate, in an amount more than about 40 times the amount of the proton pump inhibitor on a weight to weight basis in the composition.

667. (Amended) The composition as recited in Claim 666, wherein the amount of the buffering agent is sufficient to prevent or inhibit *in vivo* gastric acid degradation of the proton pump inhibitor upon the administration of the dosage form to a subject so as to achieve bioavailability of the proton pump inhibitor in the subject.

680. (Amended) The composition as recited in Claim 666, wherein the sodium bicarbonate is in an amount from about 400 mg to about 4000 mg.

681. (Amended) The composition as recited in Claim 666, wherein the sodium bicarbonate is in an amount of at least about 800 mg.

682. (Amended) The composition as recited in Claim 666, wherein the buffering agent comprises calcium carbonate.

683. (Amended) The composition as recited in Claim 666, wherein the calcium carbonate is in an amount from about 400 mg to about 4000 mg.

685. (Amended) The composition as recited in Claim 682, wherein the calcium carbonate is in an amount of at least about 800 mg.

117

D

Serial No. 09/481,207

82 57
704. (Amended) The composition as recited in Claim 666, further comprising a
flavoring agent comprising aspartame, chocolate, root beer, peppermint, spearmint, or
watermelon, and combinations of any of the foregoing.

717. 90 (Amended) A method of producing a liquid pharmaceutical composition
comprising: combining the dosage form of Claim 666 with an aqueous medium.

D18 [NE 718. (Amended) A method for treating an acid-related gastrointestinal disorder in a
subject in need thereof, comprising: administering to the subject the dosage form as recited in
Claim 666 via a route selected from the group consisting of oral, nasogastric, and gastric tube.

92 719. 91 (Amended) The method as recited in Claim 718, wherein the disorder is selected
from the group consisting of duodenal ulcer disease, gastric ulcer disease, gastroesophageal
reflux disease, erosive esophagitis, poorly responsive symptomatic gastroesophageal reflux
disease, pathological gastrointestinal hypersecretory disease, Zollinger Ellison Syndrome, and
acid dyspepsia.

D20 745. 111 (Amended) The composition as recited in Claim 34, wherein the flavoring agent
comprises aspartame, chocolate, root beer, peppermint, spearmint, or watermelon, and
combinations of any of the foregoing.

118

D